



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Southwest Region
7920 Elmbrook Drive
Suite 102
Dallas, TX 75247-4982

Telephone: 214-655-8100
FAX: 214-655-8130

June 4, 2002

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

02-SWR-WL-46/7

Xavier Villarreal
Chief Executive Officer
Eastern Oklahoma Medical Center
105 Wall Street
Poteau, OK 74953

Dear Mr. Villarreal:

Re: Inspection ID - 1114190012

We are writing to you because on May 9, 2002, a representative of the State of Oklahoma, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following violations of the Act at your facility:

Processor QC records in the month of 11/2001 were missing for at least 30% of operating days, for processor 2, Kodak, X-OMAT. (see 21 CFR 900.12(d)(2))

Processor QC records were missing at least 5 consecutive days for processor 2, Kodak, X-OMAT. (see 21 CFR 900.12(d)(2))

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These findings indicate that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

Because these deviations may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law which may result in FDA initiating regulatory action without informal notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially

comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, (see 42 U.S.C. 263b (h) and (i)).

In addition, the inspection report provided to you at the close of the inspection listed a deviation from MQSA standards that may compromise the quality of mammography services offered by the facility.

Phantom QC records were missing for at least two weeks but less than four weeks for unit 2, Bennett X-Ray Corp., CON+. (see 21 CFR 900.12(e)(2)).

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

1. the specific steps you have taken to **correct** all of the violations noted in this letter;
2. each step your facility is taking to **prevent the recurrence** of similar violations;
3. equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
4. sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

Please submit your response to:

Deborah M. McGee, Radiation Specialist
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 extension 138.

Sincerely yours,


Gary L. Pierce
Regional Food and Drug Director